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09/100,100 06/19/98 ROSS JR.

J RLIS

EXAMINER

TM02/0727

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ART UNIT

PAPER NUMBER

2164

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

09/100,100

Applicant(s)

ROSE, JR.

Examiner

KANOF

Art Unit

2164

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

THE REPLY FILED _____ FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

4. ☐ Applicant's reply has overcome the following rejection(s): _____

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because:

PLEASE SEE ATTACHMENT

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 25-29 & 37-65

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
0. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
1. ☐ Other: _____

VINCENT MILLIN

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 2100
Part of Paper No.

ADVISORY ACTION

Application No. 09/100,100

Applicant: Ross, Jr.

ATTACHMENT

The two 131 Affidavits submitted by the Applicant taken together overcomes the rejection in the Final Rejection dated 4/9/2001.

Two new references have come to the Examiner attention subsequent to said Affidavit. They are:

1. Grossman, Jerome H.; Plugged-in medicine; Technology Review; Cambridge; Vol. 97, No. 1; page 22 (+8); January 1994.
2. Lowe, Henry J. et al.; Building a medical multimedia database system to integrate clinical information: an application of high-performance computing and communication technology; Bulletin of the Medical Library Association; Vol. 83; No.1; January 1995.

These references are attached. The dates of these references are 1/1994 and 1/1995

A new Final Action will be issued with these references.

Examiner: Pedro Kanof
A.U.: 2164
Paper No. 18.


VINCENT MILLIN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2100

Plugged-in medicine

Technology Review; Cambridge; Jan 1994; Grossman, Jerome H

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Abstract:

Technologies for improving and managing the production process of health care have been emerging over the past decade. They include clinical decision-making systems, advanced information and management-support systems, and multimedia communications networks. Together they may be regarded as the tools to reengineer medical practice: all are designed to help the health care system perform better by providing improved care at lower costs. As doctors and institutions pursue this vision of efficient health care based on outcomes, complexities arise that cry out for technological solutions. First, there is the tremendous volume of new information that must be processed. At the same time, providers must contend with the high degree of fragmentation that exists within the health care system.

Full Text:

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When one thinks of technology in health care, the first things that usually come to mind are medical advances: gene therapy, laser surgery, diagnostic imaging, and the like. Indeed, this is where we have put our greatest efforts in the post-World War II era of biomedical science. But a different kind of health-care technology, less flashy and less likely to make headlines, has been emerging over the past decade, and may soon equal or surpass high-tech therapies in importance. These are technologies for improving and managing the "production" process of health care. They include clinical decision-making systems, advanced information and management-support systems, and multimedia communications networks. Together they may be regarded as the tools to reengineer medical

practice: all are designed to help the health-care system perform better by providing improved care at lower costs.

The rise of health-care management technology mirrors the shift in priorities that is gradually taking place in the medical community. As the public debate over health-care reform has made clear, providers have put too much emphasis on inputs and too little emphasis on outputs, or "outcomes." That is, we have mistakenly focused on delivering more and better tests and procedures instead of on improving the health, well-being, and satisfaction of patients.

Under the old way of thinking, providers have not been paid to maintain or restore health; we have been paid to dispense units to serve. If the price of lab tests and medications goes up, patients are charged more, regardless of whether there is a better end product. In traditional fee-for-service payment plans, we have been rewarded for making the greatest use of inputs, regardless of their effect on the patient's condition. The more we do, the more we earn. Accordingly, we have steadily improved the clinical tools at our disposal for diagnosing and treating disease. Yet we have paid much less attention to the bigger picture: how to produce the best outcomes for the patient as efficiently as possible. Progress toward this goal has not even been measured, let alone rewarded.

Over the past decade, several developments have moved us toward a new way of thinking. The marketplace, spurred by a large employers and governmental payers, has begun demanding value by purchasing health care more selectively and by trying to define and measure quality. Managed-care plans like health maintenance organizations, which pay providers a set amount of care for a certain population for a certain period of time, have proliferated. In 1983, Medicare introduced a payment system in which it gives hospitals a single, predetermined sum for each

admission, according to the patient's diagnosis-related group (DRG). As a result of these changes, providers have begun devoting more attention to the efficiency and effectiveness of the care they dispense.

Under this new way of thinking, the service that medicine provides is integrated health care rather than discrete units of things done for patients. Depending on the patient's needs, the integrated service might take the form of routine health maintenance, treatment of an illness or injury, or management of a chronic disease. Providers and payers set price levels for their reasonable costs, and except in unique cases providers must live within these established revenue limits.

Such a system dramatically changes the incentives within the delivery system. With revenues prepaid and predetermined, each service unit becomes an expense, not a source of income. The costs of each element of care must be weighed against its benefits to identify the most cost-effective process. At the same time, the outcome--the health and satisfaction of the patient--is measured and monitored, so that cost control works together with quality assurance to minimize the incentive to underutilize services.

As doctors and institutions pursue this vision of efficient health care based on outcomes, we run into complexities that cry out for technological solutions. First, there is a tremendous volume of new information that must be processed. The already overwhelming amount of data a physician must assimilate on patients' history, condition, and treatment is being compounded by new layers of information on their emotional well-being and how well they function at home and at work. As the variables multiply, it is becoming harder for a doctor to know which ones are critical for making clinical decisions. Hospital administrators, meanwhile, must be able to track and organize a welter of data to distinguish between necessary and inappropriate services, to identify opportunities for greater efficiency, and to project the cost implications of substituting one form of treatment for another.

At the same time, providers must contend with the high degree of fragmentation that exists within the health-care system. Communication barriers stand between the various provider units (primary care and specialist physicians, hospitals, laboratories, rehabilitation and nursing home facilities, and home health providers); between the providers, the health plans, and the payers; and between the patient and the health-care system. These barriers need to be minimized so that caregivers can consult together effectively, and so that information about a patient can reach everyone who should know as quickly as possible. Different departments within a hospital also need to be able to pool information to help document how well the institution is serving its patients and payers.

To relieve these problems, health-care providers are turning to sophisticated information and networking technologies. Computerized information systems can help clinicians make better decisions about how to treat individuals and groups of patients, as well as help administrators make decisions about the resources and processes that affect that treatment. Networks and other communications technologies can help fuse the many components and players into a seamless fabric of care. Such systems are gradually transforming the way we practice, the way we organize and manage care, the way providers relate to each other, and the way patients relate to the medical community.

CONSULTING COMPUTERS

The work of physicians involves endless testing of hypotheses and posing of questions: What is the patient's diagnosis? What test should I do to confirm the diagnosis? What is the best treatment? How is the treatment working?

In arriving at a decision and recommendation, physicians of course rely on their own judgment and experience, on the relevant literature, and on established clinical guidelines for treating different types of patients. But valuable as these resources are, there are still occasions when the answers are not clear. In an emergency, for example, the doctor may not have time to refer to the literature or search for the latest guideline. And the clinical guidelines for a certain condition, even if readily available, might not take into account the peculiarities of the case at hand: the patient's age, sex, and race; the stage of disease; the presence of other medical conditions; and special risk factors--like allergies. An error can prove costly, both in dollars and, more important, in the patient's health and survival.

Physicians at my hospital, New England Medical Center, are working on two types of compute-assisted "decision support" techniques for just such circumstances. One approach is intended to help physicians make accurate diagnoses in emergencies. The other will help determine the best course of treatment for individuals or groups.

In addressing emergency decision making, our goal is to develop accurate and easy-to-use instruments that can isolate the most important variables and calculate the probability that the patient is or is not going through a crisis that calls for some specified action. One such device developed by our researchers and now in trial use is the Acute Cardiac Ischemia Time-Insensitive Predictive Instrument. ACI-TIPI (pronounced "A.C.I.-tippy") helps emergency-room physicians quickly determine the probability that a suspected heart attack is real. A correct diagnosis is of paramount importance, both medically and economically. Each year, 1.5 million patients are admitted to coronary-care units, yet fewer than half are actually experiencing, or about to experience, a heart attack. These unnecessary admissions cost

over \$3 billion a year. More costly in lives is the opposite sort of mistake: some 20,000 heart attack victims each year are sent home from emergency rooms without treatment.

In the emergency room, an electrocardiograph is outfitted with a special ACI-TIPI computer program. The physician enters a few items of information, such as the patient's age and gender and whether chest pain is the chief complaint, and generates an electrocardiogram (EKG). The program analyzes these factors along with three EKG-related features, and then computes the probability--from 0 to 100 percent--that the patient is suffering from acute cardiac ischemia (a severe reduction of blood flow to the heart) and prints it on the EKG. The entire procedure can be completed within minutes of the patient's arrival, instead of the several hours it takes to perform a blood test that can confirm a heart attack. That time difference can be critical. A two-year study of an ACI-TIPI prototype found that its use reduced unnecessary coronary-care admissions by 30 percent. Projected to ever; U.S. hospital, that figure would translate into 250,000 fewer admissions each year, as well as a saving of perhaps \$1 billion in unnecessary health-care costs. The latest version of ACI-TIPI, which is easier to use than the prototype, is now undergoing clinical trials on some 15,000 patients at 10 hospitals around the country.

For non-emergency care, researchers at New England Medical Center are collaborating with MIT's Laboratory of Computer Science to develop computerized "expert systems" that help doctors make the most sensible treatment decisions in complex cases. Some of these tools quantify the risks and benefits--both clinical and economic--of different strategies for treating a given condition. They are proving useful for resolving dilemmas in treating coronary artery disease and diabetes, performing heart transplants, diagnosing prenatal and neonatal conditions, and other situations. These systems offer physicians choices in the form of a "decision tree," allowing them to see the possible ramifications of each step: If a patient receives surgery instead of medication, what is the probability that complications will set in? If the complications are treated with drugs, what is the probability that the patient will live? If the patient lives, what is the probability that he or she will suffer from a chronic impairment? And so on.

Such decision trees can be tailored to include a patient's individual preferences and risk factors such as age, sex, and the presence of secondary conditions. For example, a decision tree we developed in collaboration with Duke University examines the choice among bypass surgery, less intensive angioplasty, and medical therapy for chronic stable angina. Such models might take into account that the patient would rather live with some pain than receive a treatment that carried a risk of stroke. Other models being developed jointly at New England Medical Center and MIT are designed to help physicians predict a patient's response to drugs.

THE PLUGGED-IN PHYSICIAN

Beyond helping doctors make decisions in unique or difficult situations, information technology can serve as an invaluable aid to physicians in routine practice. In particular, the automated collection, analysis, and transmission of data allows doctors to get the information they need when they need it. The result is better clinical care, more efficient and patient-friendly service, and higher job satisfaction for caregivers.

The physician stands at the center of a swirl of information--from patients, from labs and radiology departments, from specialists. Today, most transactions in health care do not exist in any computerized system, and the systems that do contain such information are not integrated. But in the emerging computerized health-care environment, information from one office or lab can be flagged and delivered to another office or lab according to rules and criteria that the users themselves have written.

In the traditional, nonintegrated environment, test results remain in a lab's computer until a batched group is transmitted to another computer, or else individual results are manually flagged and reported by phone or fax, whereupon the message waits until the physician can be found. The latest "intelligent message routing" systems offer physicians a menu of rules and options: which results should be routinely transmitted, what kinds of readings warrant an immediate notification, where else results should be sent. If a test result is required before a patient can be discharged, for example, a doctor might order that this information be phoned in immediately and that a specialist receive a copy. The intelligent message routing system screens lab transactions, flags the ones meeting the defined rules, and transmits information to the requested parties, whether by electronic mail, fax, or paging device. The rules can also require that receipt of the information be acknowledged, or that the message be repeated at defined intervals.

For intelligent message routing to work on a large scale, the health-care system must become far more computerized. Just as important, systems in different locations must be able to communicate. Fortunately, we no longer need to rely on expensive proprietary solutions in which systems can be integrated only if the hospital works with a single vendor. The trend toward open, nonproprietary standards--such as Simple Mail Transport Protocol and Dynamic Data Exchange--allows us to create software that integrates bits and pieces of the health-care operation as needed.

MANAGING THE PROCESS OF CARE

The new combination of rules-based technology and standard interfaces between systems can help hospitals monitor and improve the overall efficiency and effectiveness of the care they deliver. In the past, each component of a hospital information system--general ledger, payroll, billing, and medical records--would collect and report its own data. The new systems, in contrast, link these types of data together to show how each unit of service affects the overall cost and quality of care.

Since the 1980s, New England Medical Center has been using systems to analyze the course of treatment for different groups of patients. For example, we can lump together all the admissions for diabetes and track these patients' care: length of stay, tests and procedures performed, costs, and clinical outcomes like readmissions. We can look at subsets of patients by age, other medical conditions, or physician. In the process, we might find that extra lab tests add no value, that one physician's patients tend to stay longer without any difference in outcomes, or that patients who received one medication did just as well as others who were given a more costly drug. This information is valuable for clinicians and managers alike.

More recently, we have applied rules-based processing to define ideal clinical protocols that providers should be following. The protocols may govern the overall process of care--for example, what should be done to a certain type of patient on day one of hospitalization, day two, day three, on through discharge. Or they can govern specific components of care--recommending, say, that antibiotics not be used for more than two days after surgery unless an infection is diagnosed. We then write rules telling the system to flag and report variations from these protocols, giving staff the opportunity to intervene. We can also monitor retrospectively how actual performance compared with the defined protocol, or how outcomes changed as a result of managing care according to the protocol. Armed with this information, we can alter our practices as appropriate.

One information system known as HELP (for "health evaluation through logical processing"), developed at Salt Lake City's Latter Day Saints Hospital, has been used to improve the way the hospital administers antibiotics. The system triggers reminders to give antibiotics to certain patients before surgery. Similarly, it issues automatic stop orders for patients who appear to have been left on antibiotic therapy too long, and notifies the pharmacist and the physician. When an infection is suspected but the agent is not known, the computer helps the physician choose the most effective antibiotic; using its own statistical analysis, HELP has selected the right antibiotic 94 percent of the time, a better rate than that achieved by physicians. The system also identifies cases where a less expensive antibiotic can be substituted for the one prescribed.

In the future, we hope to incorporate a wider variety of data into these systems. A notable example is information on patients' emotional well-being and ability to function as reported in questionnaires at various points during and after the care process. This is a new and valuable measure of how well we are serving our patients. We also need to include data from settings other than the hospital--such as doctors' offices, labs, and outpatient clinics--in order to model and analyze the process of care across a full episode of illness. Over time we hope to integrate information from other institutions and from the research literature, so that users have more material from which to draw.

TYING IT ALL TOGETHER

Just as integrating different sources of information can help institutions refine their practices, it can also reduce the fragmentation among the many players involved in a patient's care and treatment. The challenge is to bridge the barriers of space and time to meet the needs of individual patients and to make smooth and efficient processes routine. Our goal is a seamless health-care system whose components work in harmony to respond to the needs of patients, regardless of where they happen to be within the system, and even if they are at home.

To a degree, the necessary bridges can be built with existing information technology. Intelligent message routing, for example, can be extended to include not just different units of a hospital but other organizations such as the payer or a nursing home. Referral forms from an internist can be delivered to the specialist and the managed care plan at the same time. And hospital reports on the eve of discharge can be electronically mailed to the recuperative facility or the home health agency that will follow the patient.

Transmitting information across sites is more difficult than within a single institution, but the necessary infrastructure is being built. One breakthrough that will affect all industrial fields, including health care, is the introduction of asynchronous transfer mode, or ATM, a switching technology that breaks digital transmissions down into small, standardized "cells," several of which can be processed at once. With ATM, vast amounts of data will be transmitted at higher speeds and lower costs than is now possible. Such advances not only will allow information to flow easily across distances but also will accommodate multimedia communications--the transmission of voice, data, still images, and video.

Using multimedia communications networks, doctors will be able to view clinical information and consult together anywhere, anytime. A physician in one location could participate in a patient exam, or even an operation, done by

another physician someplace else. Such networks will also connect facilities, making equipment at a teaching hospital available to a community hospital. A number of demonstration "telemedicine" systems, sponsored by telecommunications companies with the participation of health-care institutions and providers, are already in the works. Bell South's planned North Carolina Information Network, for example, will put rural clinics in touch with specialists at research hospitals, allowing them to communicate by voice and video and share computer data and graphics. With this sort of technology, we will be able to eliminate much of the physical movement of caregivers and patients that now takes place and at the same time improve the quality and cost-effectiveness of care.

The next step is to link the patient at home to the health-care system. Since the 1980s, institutions have attempted to contain costs by cutting down on inpatient care. But for patients with chronic illnesses requiring frequent medical attention, and no less for their families, managing at home can be a daunting task.

In 1991, New England Medical Center and IBM Research launched a joint effort to develop an interactive home-based computer support system for the care of children with leukemia. Prototypes are now being installed. The system is meant to serve as a user-friendly educational resource and to provide clinicians with progress reports directly from the patient. The unit incorporates videos showing how to change bandages or care for catheters, as well as videos of different families and caregivers discussing clinical and emotional aspects of the illness. The computer is connected to the hospital through electronic mail. The unit is easy to use, with touch screens and directories for gaining access to stored information on symptoms, technical aspects of care, or emotional and family issues. Planned for the future are an electronic patient-support network that will link patient's who have similar conditions, a hospital-based bulletin system for news of important developments, and full-motion video transmissions between doctor and patient.

This type of home interface provides numerous benefits. It gives families the information they need to participate in the care process more directly. It reduces the disruptions to family life by lowering the number of trips to the hospital or physician's office. It establishes a feedback loop between home and caregivers for monitoring the patient's physical and emotional state and compliance with the prescribed treatment, letting staff use their time more efficiently. And contrary to what one might expect, the technology actually humanizes care by addressing the emotional needs of the patient and family, and by easing the family's anxieties about tending to their ill member.

The link between the homecare patient and the caregiver will soon become even stronger: schemes are now under development for providing patients with instruments connected to a home computer that is in turn linked to an information network. If the patient needs regular electrocardiograms, a mobile machine at home would transmit the readings in real time to the EKG lab and the physician's office. A patient whose blood pressure must be monitored could insert one arm into a cuff attached to a computer, which would immediately read results into the medical record and flag any exceptional readings for the physician's urgent attention. Technologies like these will be a major step toward establishing the continuity of care that has eluded the medical profession for so long.

OVERCOMING OBSTACLES

Like virtually any effort to change institutions and ways of operating, the transformation of health care through information technology is encountering some obstacles. One is cost. For many hospitals and physician practices, sophisticated information and networking systems are simply too expensive. Fortunately, prices are coming down as the underlying technologies mature. Just as we can purchase high-powered personal computers today at prices that were unimaginable a decade ago, information technology will continue to undergo an exponential increase in performance with an exponential decrease in costs.

More good news is that organizations able to afford these technologies will find their investment quickly repaid. In one recent study (conducted in Minnesota and Virginia by the Tiber Group, a Chicago-based consulting firm), electronic filing of health-care claims and other paperwork was found to yield annual savings ranging from \$30799 for small hospitals to \$1.4 million for larger hospitals, and from \$13,000 for small physician practices to \$183,000 for larger practices. Start-up costs were only \$21,000 to \$12,000 for hospitals and \$4,000 to \$13,000 for medical practices. The authors concluded that conducting 85 percent of all transactions electronically would save the health-care industry \$4.7 billion a year. As more studies show the financial benefits of new information systems, the expense will be easier to justify.

But technological change also runs up against human barriers. At first people may be intimidated by new computer systems, regardless of how user-friendly they may be. In some instances the new information systems will change the essence of people's jobs, for better or worse. For example, hospital staff who monitor the quality and cost of care now spend much of their time poring through reports to identify incidents that fail to meet specified criteria. With new systems that automatically flag variances, the staff occupy themselves with the more challenging task of analyzing the causes, effects, and solutions.

Designing and installing new systems must be a cooperative venture between developer and user. As much as possible, the new products should take into account the user's needs and habits. The ACI-TIPI system for identifying heart attacks, for example, was originally designed in the form of a calculator, which is not a standard part of the physician's "toolkit." Incorporating the system into an electrocardiograph made it more palatable.

In the past, the conservatism of the health-care community has caused it to lag behind other industries in applying information technology to help manage production processes. But now we must surge ahead. The Congressional Research Service has estimated that about half the growth in health-care expenditures is controllable--that is, unrelated to general inflation or population changes. As the emphasis in medicine shifts from inputs to outcomes, the incentives are growing for physicians to provide high-quality, cost-effective care. Advances in information and networking technology can accelerate this trend by helping care providers determine the most direct, most effective, and least costly means of diagnosing and treating patients. Such technologies offer the tools to redefine and restructure health care in our time.

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Building a medical multimedia database system to integrate clinical information: an application of high-performance computing and communications technology*†

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The rapid growth of diagnostic-imaging technologies over the past two decades has dramatically increased the amount of nontextual data generated in clinical medicine. The architecture of traditional, text-oriented, clinical information systems has made the integration of digitized clinical images with the patient record problematic. Systems for the classification, retrieval, and integration of clinical images are in their infancy. Recent advances in high-performance computing, imaging, and networking technology now make it technologically and economically feasible to develop an integrated, multimedia, electronic patient record. As part of The National Library of Medicine's Biomedical Applications of High-Performance Computing and Communications program, we plan to develop Image Engine, a prototype microcomputer-based system for the storage, retrieval, integration, and sharing of a wide range of clinically important digital images. Images stored in the Image Engine database will be indexed and organized using the Unified Medical Language System Metathesaurus and will be dynamically linked to data in a text-based, clinical information system. We will evaluate Image Engine by initially implementing it in three clinical domains (oncology, gastroenterology, and clinical pathology) at the University of Pittsburgh Medical Center.

BACKGROUND

Patient care generates a large amount of text-based data. The sheer volume of this clinical data and its increasing importance to health care activities has begun a trend toward the use of computerized clinical information systems [1]. Many of these systems are entirely or largely text oriented. However, text is only

one medium through which clinical information is recorded and communicated.

The rapid growth of diagnostic imaging technologies over the past two decades has dramatically increased the amount of nontextual data generated in clinical medicine. Imaging technologies are essential to the modern practice of clinical medicine [2]. Traditional radiological and nuclear medicine images are now complemented by computerized tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), ultrasonography, and endoscopy-generated image data. Health care providers use such images routinely to make clinical decisions. Furthermore, many medical specialties such as pathology, dermatology, and ophthalmology generate a large number of clinically important images.

Though reports on these images are added to the

* Based on a presentation at the Medical Library Association's Ninety-Fourth Annual Meeting postconference symposium, "Building the National Health Information Infrastructure: The Role of High-Performance Computing and Communications," San Antonio, Texas, May 19, 1994.

† This project is supported by Biomedical Applications of High-Performance Computing and Communications (BAA/HPCC) Contract no. NO1-LM-4-3507 from the National Library of Medicine.

Lowe et al.

patient record, the images themselves are usually difficult for the clinician to access and often impossible to integrate with other relevant clinical data [3]. Systems for the classification, retrieval, and integration of clinical images are in their infancy [4]. Traditional picture archival and communications systems (PACS) [5-7] are generally expensive, monolithic solutions that serve primarily the needs of radiologists and are often not well integrated with the patient record. The new clinical imaging technologies demand innovative medical image database models that can integrate all patient data. Such systems may improve the quality of patient care [8-9], increase the patient's involvement in clinical decision making [10-11], and produce significant new medical knowledge [12].

The architecture of traditional, text-oriented, clinical information systems has made the integration of digitized clinical images with the patient record problematic. This lack of integration leads to a fragmentation of the patient record, which hinders the physician's ability to synthesize all the data relevant to clinical decision making. In part, this partitioning of textual and nontextual patient data reflects the technological heritage of the traditional patient record. Until recently, the technology required to integrate textual and image-based clinical information was prohibitively expensive or nonexistent. Recent advances in high-performance computer, imaging, and networking technology now make it technologically and economically feasible to create a truly integrated, multimedia, electronic patient record linking digitized clinical images from a wide variety of sources with the traditional, text-based, medical record.

BEYOND PACS

Although PACS [13-14] have been an active area of research and development for almost twenty years [15-16], much of that work has been within the domain of radiology and has focused on expensive institutional systems [17]. Some involved with PACS research feel that if the fundamental idea is to prosper, it must expand its domain from radiology and radiologist to a broad range of clinically important images and the majority of physicians practicing both inside and outside the hospital environment [18]. In addition, given the current fiscal outlook for health care delivery, we must seek ways to reduce the implementation costs of integrated clinical image delivery systems.

The integration of clinical images with the textual clinical record has been an area of increasing interest over the past few years. Although a number of integrated PACS systems are described in the literature [19-20], one of the most innovative implementations of integration has been in the Department of Veterans Affairs (VA) Decentralized Hospital Computer Pro-

gram (DHCP) [21-23]. This system, developed at the Washington Information Systems Center of the VA, is a "distributed imaging system that provides image management and communications functionality as an integral part of its existing integrated hospital information system" [24]. The DHCP is an object-oriented system based around the MUMPS VA File Manager database using UNIX/X Windows or Microsoft Windows workstations and multiple image servers. It goes beyond the traditional PACS radiology model by "handling a variety of medical images including cardiology studies, microscopic pathology slides and endoscopic examinations" [25].

There is currently a confluence of developments that makes it technologically and financially feasible to implement institutional systems integrating digitized clinical images from a wide variety of sources with the traditional medical record. These innovations include inexpensive microcomputer workstations with the processing power, memory, and display characteristics necessary to permit real-time decompression and display of high-resolution digital still images and digital video. Image compression technology is now widely and inexpensively available, and international compression standards are emerging [26]. Digital video technology is now an integrated part of many microcomputer operating systems and permits us for the first time to display real-time, on-screen, color-video sequences using widely available and affordable computers. Networking advances increasingly supply the necessary bandwidth for institutional transport of compressed digital images.

Image compression will be an important enabling technology in the development of integrated, multimedia clinical information systems. Even with current advances in affordable computer hardware, the large size of uncompressed images would preclude workable, large-scale systems. For example, one minute of digital video (480 by 640 pixels, 24-bit color at 30 frames per second) requires 1.5 gigabytes of storage, while a single 480 by 640 pixel, 24-bit color still image is approximately one megabyte in size. Clinical information systems working with uncompressed data of this scale would rapidly fill even today's gigabyte storage devices and jam most institutional networks.

IMAGE ENGINE

Our Biomedical Applications of High-Performance Computing and Communications (HPCC) contract from the National Library of Medicine (NLM) will allow us to further develop Image Engine, a prototype microcomputer-based system for the storage, retrieval, integration, and sharing of a wide range of clinically important digital images [27]. Images stored in the Image Engine database will be indexed and or-

ganized using the Unified Medical Language System Metathesaurus and will be dynamically linked to data in a text-based, clinical information system. We will evaluate Image Engine by initially implementing it in three clinical domains at the University of Pittsburgh Medical Center (UPMC): oncology, gastroenterology, and clinical pathology.

The Image Engine System architecture consists of three layers: the Server Layer, the Object Database Layer and the Image Browser Layer. In addition, Image Engine will make use of two network-based services: the Medical ARchival System (MARS) clinical information system and the Probabilistic Indexing (Pindex) server.

THE MARS CLINICAL INFORMATION SYSTEM

MARS is a text-based, clinical information system developed by Dr. John Vries and Russell Yount at UPMC [28]. MARS has been in operation at UPMC for five years. It contains approximately 3.2 million whole-text, word-indexed, clinical records. These document records contain the full text of patient histories and physicals; operative and procedure notes from multiple clinical specialties; discharge summaries; laboratory results; and reports from the pharmacy, microbiology, pathology, and radiology departments. The data stored on MARS includes 80% of all information generated at UPMC and all information produced by the Central Transcription Service for UPMC's hospitals and outpatient clinics. More than 2,500 registered users retrieve an average of 5,000 reports each day, and these numbers are growing steadily. MARS is available twenty-four hours per day. It is anticipated that by 1995, MARS will capture most of the clinical information generated at UPMC.

THE PINDEX INDEXING SYSTEM

We have developed a system called Pindex that takes as input a string of free text and returns an associated list of Medical Subject Heading (MeSH) terms that are each annotated with a probability of relevance. The development of Pindex has been supported in large part by the NLM UMLS project. We are modifying and extending Pindex for the task of indexing images. We plan to use this modified version of Pindex to index medical images based on their free-text descriptions and to assist users retrieving images given free-text input from the user about the type of images that are desired.

Pindex works as follows. A simple parser, P , converts free text input into a set of word phrases, which we denote as S . Pindex has a large table, T , that associates word phrases with MeSH terms. Each association between a phrase and a term has an attached

probability. Let U denote the MeSH terms that are associated with one or more phrases in S . We attach to each term in U the maximum probability it has in association with any phrase in S (as given by table T).

If the free text is a description of an image, then the terms in U can be used to index the image. If the free text is a user query, then we can sort the terms in U in descending order of their attached probabilities. The user can choose terms from this sorted list to construct a search expression for images of interest.

Table T is constructed as follows. A large group of MEDLINE articles is used as the training set. For each MEDLINE article, A_i , we apply parser P to the text in the title and abstract of the article to derive a set of word phrases, S_i . Let U_i denote the main MeSH headings assigned to article A_i in MEDLINE. In A_i , we view each phrase in S_i as co-occurring once with each MeSH term in U_i . We update table T to reflect the phrase-term co-occurrences for article A_i and phrase occurrences in article A_i . After all articles are processed, table T contains the number of occurrences of each phrase that was encountered in the MEDLINE training articles and the number of co-occurrences of each phrase-term pair encountered. From these statistics, we compute the probability of a MeSH term, u , given a phrase, s , as the total number of co-occurrences of s and u divided by the total number of occurrences of s . To avoid misleading probability estimates due to small sample sizes, we require that the value of s be greater than a minimum threshold.

The terms in table T need not be limited to MeSH terms. In general, we can construct the table using any training data that contain free-text descriptions that are annotated with controlled vocabulary terms. Thus, for example, in addition to using MEDLINE training data, one could use training data based on surgical pathology reports in the MARS system for which online SNOMED codes are available. Our overall focus will be on using training data that contain terms within the UMLS Metathesaurus.

THE IMAGE ENGINE SERVER LAYER

The Image Engine Server Layer will consist of a dedicated server computer and a number of gigabyte range hard disks connected to UPMC's high-speed data network. These disks will store digitized, compressed clinical images. Still digital images will be stored in the PICT format and digital video images as Quick-time files. PICT files will be compressed using the International Standards Organization's (ISO) Joint Photographic Experts Group (JPEG) still image compression algorithm [29-30]. Digital video files will be compressed with the proposed ISO Motion Picture Experts Group (MPEG) video compression scheme [31]. Storing images in these widely supported and well-

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documented formats will facilitate cross-platform development and image sharing. We plan to support image translation between a number of standard image interchange formats.

One of the issues we will address with image domain experts is defining the optimal compression characteristics for different clinical image types. Images will be automatically compressed as they are added to the server database and decompressed on arrival at a workstation running the Image Engine Browser software. Image compression reduces disk storage requirements and reduces transfer time across the network. While the ISO standard JPEG is lossy at compression ratios above 2:1, it is often capable of compressing a wide range of still image types at compression ratios of 10:1 to 24:1 without detectable loss of image quality. (Lossless image compression means that although the storage requirements of an image are reduced and the image is therefore compressed, the data set for that image remains unchanged. Lossy image compression, on the other hand, means that in the process of compressing an image, some of the original image data set is irreversibly lost.) For example, formal clinical evaluation of JPEG compressed chest x-rays found a compression ratio of 20:1 or less to be acceptable [32]. The optimal degree of compression applied to any image type is highly dependent upon the nature of the image [33] and will have to be determined over time in consultation with image domain experts.

THE IMAGE ENGINE OBJECT DATABASE LAYER

The Object Database Layer uses an object-oriented database model to represent the images stored on the Image Engine Server [34]. This may be viewed as a virtual database, in that it integrates data stored both locally and (by reference) on other systems [35]. This approach has a number of advantages, including avoiding storage replication and problems with data version inconsistencies. This model also allows for future integration with other clinical information systems.

The Image Engine Object Database will contain object-oriented representations of the images stored on the server. This database structure will support multiple independent index files. Each image object record will have a unique identifier. Object property values will be indexed as either text (inverted word-stem index based upon the Porter Algorithm [36]) or data (indexed on full property value). In addition, we are interested in experimenting with data by reference models (virtual data existing in other database systems). Multiple indexes based upon property values will allow for rapid database searching on many independent criteria.

Figure 1 outlines the major elements of the Image Engine Database and its relationship to MARS and Pindex. The image itself is stored in the server layer and has an object representation in the Image Engine Object Database. Each image object has a set of property values. For simplicity, only some of the image objects property slots (e.g., Image Reference, Patient ID) are shown. All image objects in the database will be indexed by multiple property keys in the Image Engine Index. These property keys point to both the Image Object and the image itself. Thus the index can be used to find a specific image or a set of images meeting some specification. Property values can also point to data stored on MARS (i.e., data by reference). For example, the Patient ID property points implicitly to all the MARS documents for that patient. Combinations of properties can define subsets of MARS data; for example, all pathology reports for a given patient ID between date X and date Y. Pindex is shown in this figure in its role as an automatic indexing tool, taking document input from MARS and sending Metathesaurus terms to the Object Database. However, Pindex could also aid data retrieval by taking text from a user query and returning suggested Metathesaurus terms for use in image retrieval.

THE IMAGE ENGINE BROWSER LAYER

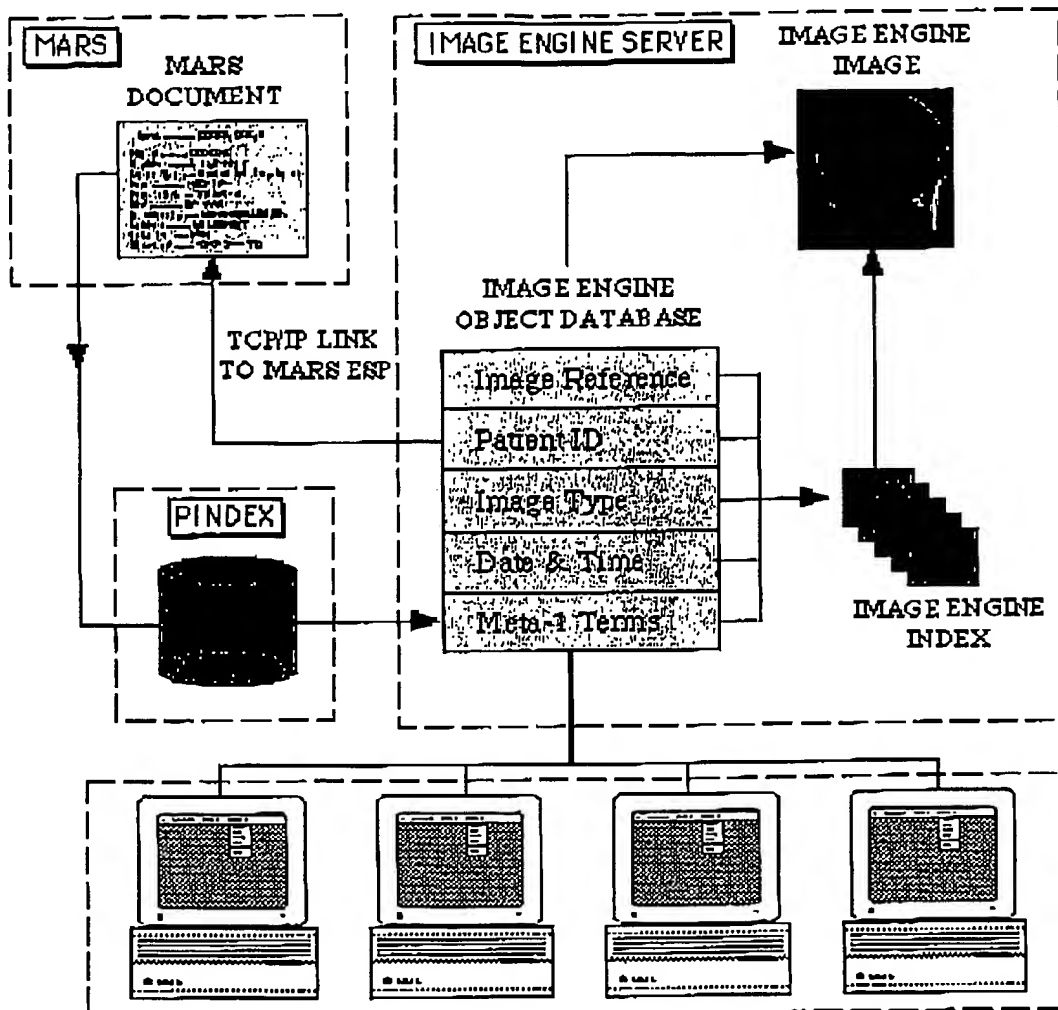
The Image Engine Browser (Figure 2) is a client application that allows one to interact with the Object Database through an easy-to-use graphical user interface. The Browser communicates with the Object Database over the network and uses a client-server model to request and retrieve image and patient data. Currently the project's workstations are based on Apple Power Macintosh 7100/66 RISC systems with twenty-four megabytes of RAM and twenty-inch, 1,152 by 870 pixel resolution color monitors using accelerated, twenty-four-bit color video cards.

The user may search for image subsets using combinations of image properties, including Metathesaurus terms. Retrieved subset summaries of images can be viewed as either a scrollable list of thumbnail images (100 by 100 pixel scaled, 24-bit color images) or a text list of object identifiers (image name, type, patient ID, and so forth). Images can be selected and viewed at full or scaled size on the computer display in resizable, scrollable windows. Multiple images can be viewed simultaneously. Image information text can be viewed simultaneously with images. Retrieved image sets can be sorted and displayed on a number of criteria.

Digital video images can be displayed on screen and controlled with videotape-like features (e.g., reverse, fast-forward, still frame, and reverse/forward frame capabilities). Users can convert digital video frames to digital still images. Given the large size of

Building a medical multimedia database

Figure 1
Structure and relationships of Image Engine Object Database



even compressed digital video sets, we wish to determine whether endoscopy data, for example, stored in short video segments have any clinical advantage over selected digitized still images extracted from the video record.

The browser will provide a set of basic image-processing functions to support image enhancement, image formal translation, and feature measurements. In addition, the Image Engine Browser will communicate with and pass images to external applications such as image processors and electronic mail clients. Image and patient data from MARS will also be viewed within the Browser. The Image Engine architecture will facilitate the future integration of clinical deci-

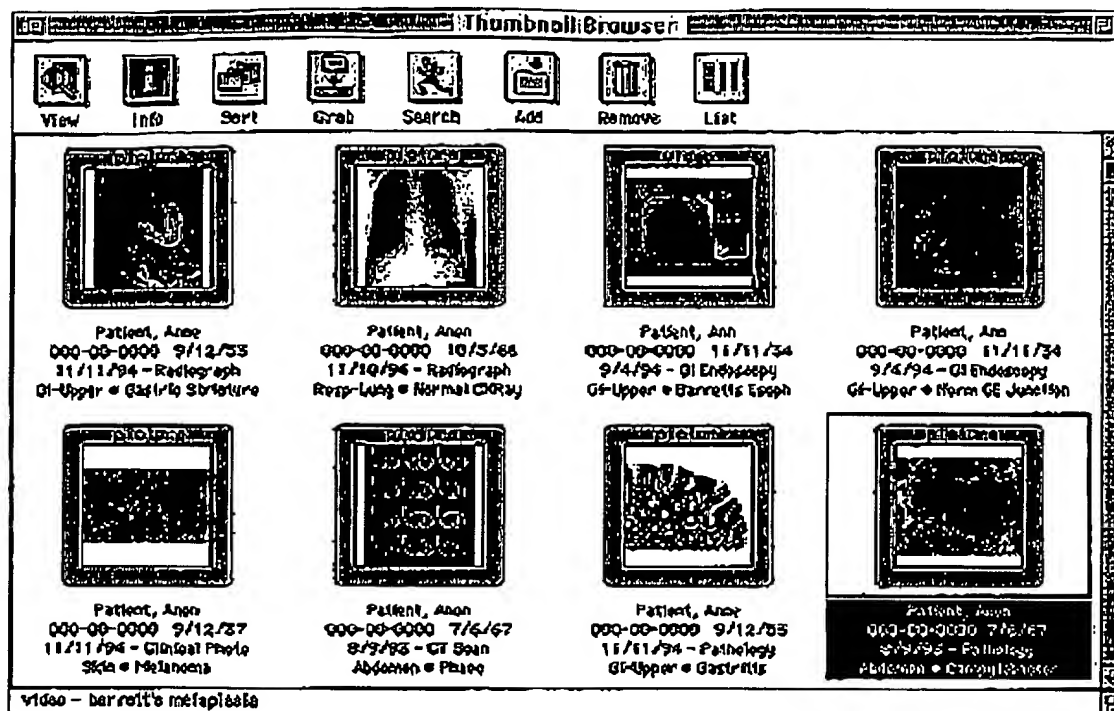
sion resources such as MEDLINE, PDQ, and clinical guidelines.

NETWORKING PROTOCOLS

The Image Engine server will be connected to the University Medical Center's network via a high-speed Ethernet connector and will initially communicate with Image Engine Client workstations at UPMC via a proprietary message-passing scheme using Apple Computer's Ethertalk networking protocol. We plan to switch to the standard transmission-control protocol/Internet protocol (TCP/IP) at a later phase of this project.

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Figure 2
Image Engine Thumbnail Browser



The UPMC data network consists of a basic backbone of three Fiber Digital Device Interface (FDDI) rings using fiber-optic cable with fiber-optic limbs to collapsed Ethernet backbones in each of the constituent hospitals and clinics of the medical center. Fiber-optic cable now extends to most hospital and clinic floors with standard 10BaseT cabling to individual workstations. The current average data transfer rate is ten megabits per second, increasing to a maximum of 100 megabits per second in the near future, with the installation of Level-5 cabling. The current supported routing protocols include TCP/IP, Novell's Internetwork Packet Exchange (IPX), and AppleTalk. Current bridging protocols include Digital Equipment's Local Area Transport (LAT) and Local Area Storage Transport (LAST), and Maintenance Operations Protocol (MOP).

DYNAMIC LINKS TO A TEXT-BASED CLINICAL INFORMATION SYSTEM

The MARS database system supports a scripting language, called ESP, which we will use to implement

dynamic links between clinical images in the Image Engine database and associated patient information in the MARS database. Using ESP, an application on the UPMC data network, can establish a TCP/IP connection to the MARS ESP server and transmit MARS queries written in the ESP language. MARS patient data retrieved by an ESP query is returned over the network to the requesting application in a format defined in the ESP query script. ESP, therefore, allows an application to become a MARS client.

The MARS ESP query language is still under development, and we anticipate that our work on dynamically linking Image Engine objects to MARS may suggest new features and enhancements to the ESP language and server. In particular, we are interested in exploring the use of "shortcut" ESP queries that specify exactly which documents should be retrieved. This will give us the capability of storing sparse ESP queries in Image Object property slots as data by reference. If this approach works, we could expand the Image Object Database to contain image objects that know how to retrieve information about themselves from other clinical information systems without any

user interactions. Such objects could "stack" potential data items from MARS, based upon their past experience with particular users or past sequences of actions leading to data retrieval. For example, such an object could anticipate that if a user views a colonoscopy report and associated images she may also request associated pathology images and reports. Depending upon user preference, these "stacked" images and reports might be automatically retrieved along with the explicitly requested data.

We are eager to ensure that the dynamic links between Image Engine and MARS are implemented in a way that does not preclude Image Engine linking in the future to other important clinical information systems. One method of ensuring this independence may be by defining a communications layer between Image Engine and the other databases.

CLINICAL APPLICATIONS

As part of our HPCC contract, we plan to install and evaluate Image Engine workstations in three clinical environments at UPMC—clinical pathology, gastroenterology, and medical oncology.

In clinical pathology, we will focus on issues involved in digitizing, compressing, indexing, storing, and retrieving both gross and microscopic pathology images. Clinicians in the gastroenterology and oncology test sites will identify pathology specimens (for example, biopsies obtained during gastrointestinal endoscopy or diagnostic oncology procedures) from patients entered into the Image Engine database. These pathology specimens will be digitized, indexed, and added to the database. Image Engine will automatically integrate these pathology images with other digitized images (such as endoscopy and radiology) and the text-based clinical record for that patient.

In gastroenterology, we will work with clinicians specializing in fiber-optic endoscopy of the gastrointestinal and biliary tracts. These domains will involve digital still and video images, pathology images, and radiological imaging studies (including MRI, CT, and ultrasound). For patients entered in the Image Engine database, it will be possible for clinicians to selectively view and manipulate integrated image and textual data.

In medical oncology, we will explore how one manages and integrates the wide range of images (including radiology, MRI, CT, pathology, and clinical photography) that are used in the diagnosis, staging, and treatment of patients with solid tumors. Clinicians will be able to rapidly retrieve both image and textual data for patients entered into the Image Engine database.

Image Engine should be useful in many other image-intensive clinical domains such as dermatology

[37] and ophthalmology [38]. In addition, as the number and variety of images in the database increases, it has the potential to become a valuable educational and research resource. For example, it would be possible for one to retrieve and view a set of pathology, dermatology, ophthalmology, endoscopy, and radiology images for a given disease entity. Alternatively, one could retrieve selected images from a population of patients with certain characteristics.

It has been estimated that medical imaging databases acquire in excess of one terabyte of information per year in a major hospital [39]. Given the large size of even compressed digital images, we have chosen to limit our initial HPCC evaluation domains to a relatively small population of clinicians and patients. Our goal in this project is not to implement a very large-scale, hospitalwide, image database system during this three-year project. Also, Image Engine is not intended to compete with or replace PACS, which we see as continuing to develop as a radiological support system. Instead, we plan to focus on the technical and clinical issues involved in creating a potentially portable system that could be scaled to handle the image storage, retrieval, and sharing needs of clinicians, with an emphasis on integrating a wide range of clinically important images with the text-based patient record using relatively inexpensive high-performance computers and networking technology.

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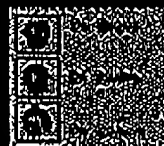
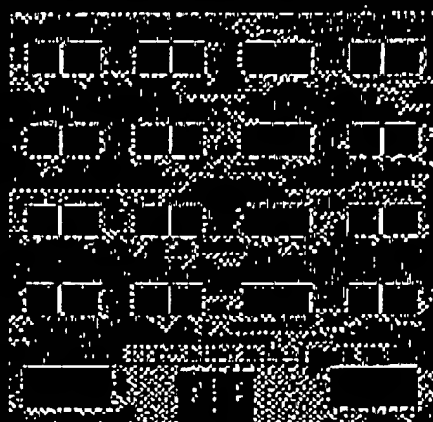
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